

10/554407

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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Substitute for form 1449B/PTO				Application Number		Unassigned- 10/554407	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date		Herewith- 10/24/05	
Date Submitted: October 24, 2005				First Named Inventor		Osamu OKUDA	
(use as many sheets as necessary)				Group Art Unit		Unassigned- 1646	
Sheet 1 of 2				Examiner Name		Unassigned <i>Penna Menz</i>	
				Attorney Docket Number		053466-0409	

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
<i>PM</i>	A1	5,210,075		Scholz et al.	05/11/1993	
<i>✓</i>	A2	6,270,766	B1	Feldman et al.	08/07/2001	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
<i>PM</i>	A3	EP	1 074 268	A1	Chugai Seiyaku Kabushiki Kaisha and Tadamitsu KISHIMOTO	02/07/2001		
<i>✓</i>	A4	PCT	WO 97/10338		Chiron Corporation	03/20/1997		
	A5	PCT	WO 99/64070		Ophidian Pharmaceuticals, Inc.	12/16/1999		
	A6	PCT	WO 2004/039826	A1	Centocor, Inc.	05/13/2004		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
<i>PM</i>	A7	BAERT, Filip et al, "Influence of Immunogenicity on the Long-Term Efficacy of Infliximab in Crohn's Disease", NEW ENGLAND JOURNAL OF MEDICINE, February 2003, Vol. 348, No. 7, pgs. 601-608.	
<i>✓</i>	A8	CHOY, E. H. S. et al, "Therapeutic Benefit of Blocking Interleukin-6 Activity With an Anti-Interleukin-6 Receptor Monoclonal Antibody in Rheumatoid Arthritis: A Randomized, Double-Blind, Placebo-Controlled, Dose-Escalation Trial", ARTHRITIS AND RHEUMATISM, December 2002, Vol. 46, No. 12, pgs. 3143-3150.	
	A9	ITO, Hiroaki et al., "A Pilot Randomized Trial of a Human Anti-Interleukin-6 Receptor Monoclonal Antibody in Active Crohn's Disease", GASTROENTEROLOGY, April 2004, Vol. 126, No. 4, pgs. 989-996.	
<i>✓</i>	A10	MAINI & CHARISMA STUDY GROUP, "A Double-Blind, Parallel Group, Controlled, Dose Ranging Study of the Safety, Tolerability, Pharmacokinetics and Efficacy of Repeat Doses of MRA Given Alone or in Combination With Methotrexate in Patients With Rheumatoid Arthritis", ABSTRACT OF PRESENTATION AT EULAR, June 2003, 2 pages.	

Examiner Signature	<i>Penna Menz</i>	Date Considered	9/25/07
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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PM	A11	MAINI, Ravinder et al., "Therapeutic Efficacy of Multiple Intravenous Infusions of Anti-Tumor Necrosis Factor $\alpha$ Monoclonal Antibody Combined with Low-Dose Weekly Methotrexate in Rheumatoid Arthritis", ARTHRITIS AND RHEUMATISM, September 1998, Vol. 41, No. 9, pgs. 1552-1563.	
	A12	NISHIMOTO, N. et al., "Toxicity, Pharmacokinetics, and Dose-Finding Study of Repetitive Treatment with the Humanized Anti-Interleukin 6 Receptor Antibody MRA in Rheumatoid Arthritis. Phase I/II Clinical Study", JOURNAL OF RHEUMATOLOGY, Vol. 30, No. 7, July 2003, pgs. 1426-1435.	
	A13	NISHIMOTO, Norihiro et al., "Safety and Efficacy of Repetitive Treatment with Humanized Anti-Interleukin-6 Receptor Antibody (MRA) in Rheumatoid Arthritis", ARTHRITIS AND RHEUMATISM, 2002, Vol. 44, No. S9-191, pg. S84, abstract only.	
	A14	NISHIMOTO, Norihito et al., "The Long-term Safety and Efficacy of Humanized Anti-Interleukin-6 Receptor Monoclonal Antibody, MRA in Multicentric Castelman's Disease", DATABASE BIOSIS "Online BIOSCIENCES INFORMATION SERVICE, November 2003, 1 page.	
	A15	WAGNER, C. L., et al., "Consequences of Immunogenicity to the Therapeutic Monoclonal Antibodies ReoPro® and Remicade®", IMMUNOGENICITY OF THERAPEUTIC BIOLOGICAL PRODUCTS, 2003, pgs. 37-53.	

Examiner Signature	<i>P. M. Muntz</i>	Date Considered	9/25/07
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